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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,076	09/18/2003	William Wolf	51259/DBP/R178	6846

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EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
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1744

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08/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/667,076	Applicant(s) WOLF ET AL.	
	Examiner Nathan A. Bowers	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- 1) Claims 1, 4-10, 13-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nemser (US 6221247) in view of Goddard (US 5468388).

With respect to claims 1 and 10, Nemser discloses a filtration apparatus and method for isolating a microorganism from a liquid. Nemser discloses that the filter (Figure 1:3,4) comprises first and second endcaps (Figure 11:114) that are engageable with an inlet end of a hollow fiber filter. This is disclosed in column 1, lines 21-30, column 2, lines 7-28, column 6, lines 29-31, and column 7, lines 16-45. From Figures 1 and 11, it is apparent that the first endcap includes a first passage having an inlet engageable with a liquid input conduit, and an outlet into the filter. The second endcap includes a second passage that is engageable with a liquid return conduit, as well as an inlet from the filter. The first and second passages are independently sized such that in conjunction with a flow restriction means (Figure 1:V1) which restricts a flow from the liquid through the second passage so that a predetermined exit liquid flow rate from at least one permeate outlet (Figure 1:115) of the filter is achieved. This is described in column 7, line 55 to column 8, line 47. During operation, microorganisms are captured within the hollow fiber filter, and the maximum working pressure is not exceeded. Nemser additionally discloses that the liquid to be filtered is derived from a finite liquid sample supply (Figure 1:2). Nemser also describes the use of a pressure relief conduit (Figure 1:7) and a pressure relief valve (Figure 1:6) designed to regulate pressures that are applied to the filter. Nemser, however, does not indicate that the pressure relief valve is arranged upon the first endcap.

Goddard discloses a microorganism filtration apparatus that includes a first endcap comprising a fluid inlet (Figure 1:4) and a second endcap comprising a permeate outlet (Figure 1:6). A pressure relief valve (Figure 1:8) is provided next to the fluid inlet and serves the

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purpose of ensuring that the maximum working pressure of the filter is not exceeded. This is disclosed in column 2, lines 1-60.

Nemser and Goddard are analogous art because they are from the same field of endeavor regarding biological filtration devices.

At the time of the invention, it would have been obvious to ensure that the pressure relief valve disclosed by Nemser is provided on the first endcap. This would have allowed the filter and relief valve to exist in closer communication, thereby allowing manipulation of the relief valve to affect changes at the filter in a more immediate manner. Goddard indicates in column 1, lines 22-29 that this type of quick response to unfavorable conditions is important because build-up of pressure within the filter module tends to reduce the effective surface area of the filter element. A relief valve represents an effective way to periodically release this build-up in a controllable fashion.

With respect to claims 4, 5, 13, and 14, Nemser discloses the apparatus and method set forth in claims 1 and 10 as set forth in the 35 U.S.C. 102 rejection above. In Table I, Nemser describes filtrate flow rates obtained during experimentation ranging as high as $234 \text{ L/m}^2\text{-hr}$. This is equivalent to approximately $4 \text{ L/m}^2\text{-min}$. Column 7, lines 17-29 indicate that 180 cm^2 surface area is typically provided for filtration. Accordingly, it is believed that Nemser anticipates exit liquid flow rates as high as 0.072 L/min , which is lower than the claimed rates. Regardless, it is believed that the flow rate of permeate is a result effective variable that is commonly optimized through routine experimentation. See MPEP 2144.05. It would have been obvious to increase the permeate flow rate if it was deemed that an increase in permeate flow

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rate is desirable. There are many methods known in the art by which one can increase the rate of filtration. These include increasing the transmembrane pressure differential, increasing the rate at which fluid is added to the filter, and increasing the filter surface area. Since these methods are known, it is believed that one would be fully capable of adjusting the exit liquid flow rate disclosed by Nemser to about 1.5 L/min if such an increase was considered to be necessary and advantageous.

With respect to claims 6 and 15, Nemser and Goddard disclose the apparatus and method in claims 1 and 10 wherein the maximum working pressure of the hollow fiber filter is about 25 psi. Column 11, lines 16-30 of Nemser indicate that the recommended transmembrane pressure gradient is 30 psi. 30 psi is considered to be "about 25 psi."

With respect to claims 9 and 18, Nemser and Goddard disclose the apparatus and method in claims 1 and 10 wherein the microorganism is either a bacteria or a virus. Column 1, lines 21-30 of Goddard indicate that it is known in the art to isolate bacteria and viruses from a biological solution using ultrafiltration. The pore sizes described in column 2, lines 12-17 are believed to be fully capable of isolating these types of microorganisms.

With respect to claims 7, 8, 16, 17, 19 and 21, Nemser discloses the apparatus and method set forth in claims 1 and 10 as set forth in the 35 U.S.C. 102 rejection above. Nemser discloses an endcap for engagement with a hollow fiber filter. The endcap includes a passage having an inlet engageable with a liquid input conduit, and an outlet into the filter. Nemser,

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however, is silent with regard to the diameter of the passage defined by the endcap. Nemser does state in column 7, lines 8-12 that the filter (Figure 11:111) connected to the passage is tubular in shape and is characterized by an inner diameter of 21 mm. Based on Figure 11, it is believed that the diameter of the tubular filter and the diameters of the passageways defined by the endcaps are similar in size. The Examiner therefore considers the endcap passages to be characterized by diameters of approximately 21 mm.

It is believed that endcap passage diameter is a result effective variable that can be optimized through routine experimentation. For the sake of argument, if it is determined that Nemser does not disclose a passage diameter of 21 mm, then it is the Examiner's opinion that it would have been obvious to adjust the diameter if it was deemed that 21 mm diameters produce desirable results. Corrections in pipe diameter represent a common way to adjust the fluid flow rates. See MPEP 2144.05.

2) Claims 2, 12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nemser (US 6221247) in view of Goddard (US 5468388) as applied to claims 1, 10 and 19, and further in view of Shettigar (US 5464535).

Nemser and Goddard disclose the apparatus and method set forth in claims 1, 10 and 19 as set forth in the 35 U.S.C. 103 rejections above, however do not expressly disclose that the hollow fiber filter is a hemodialysis filter.

Shettigar discloses a filtering mechanism similar to the one proposed by Nemser. A first endcap (Figure 2:52) is engageable with an inlet end of a hollow fiber filter (Figure 2:26), and includes a first passage having an inlet engageable with a liquid input conduit. A second endcap

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(Figure 2:50) is provided to engage the hollow fiber filter and form an outlet. Permeate is allowed to exit from a additional conduit (Figure 2:58) formed in communication with the filter. This is described in column 4, line 25 to column 5, line 13. Column 6, line 60 to column 7, line 21 indicates that the apparatus is intended for use as a hemodialysis filter.

Nemser, Goddard and Shettigar are analogous art because they are from the same field of endeavor regarding biological filtration systems.

At the time of the invention, it would have been obvious to modify the filter disclosed by Nemser so that one could use it for hemodialysis applications. In column 1, lines 14-25, column 2, lines 38-46 and column 6, line 60 to column 7, line 21, Shettigar states that it is beneficial to utilize a filter during hemodialysis in order to extract blood components for testing and analysis. In this way, it is possible to take a sample of the permeate that has passed through the filter while returning the filtered blood to the patient without incurring significant blood cell loss or affecting other blood constituents.

3) Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nemser (US 6221247) in view of Goddard (US 5468388) as applied to claim 10, and further in view of Chappelle (US 4385113).

Nemser and Goddard disclose the invention as previously described above, however do not clearly disclose a mechanism by which captured microorganisms are removed from the hollow fiber filter.

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Chappelle discloses a method of filtering water in order to capture bacteria. In column 3, line 29 to column 4, line 33, Chappelle indicates that fluids are backwashed through the filter under pressure in order to remove captured bacteria from the filter membrane.

Nemser, Goddard and Chappelle are analogous art because they are from the same field of endeavor regarding microorganism filtration units.

At the time of the invention, it would have been obvious to ensure that captured microorganisms are removed from the hollow fiber filter disclosed by Nemser. Chappelle indicates in column 2, lines 31-54 and column 4, lines 25-33 that this is advantageous because it allows one to create a concentrated bacteria sample that can subsequently be analyzed. Additionally, it would have been beneficial to periodically remove microorganisms from the filter of Nemser in order to prevent clogging and the development of a high pressure drop across the membrane. In this way, the removal of microorganisms would allow the filter to operate more efficiently.

Response to Arguments

Applicant's arguments filed 30 May 2007 with regard to the 35 U.S.C. 103 rejections involving the combination of Nemser and Goddard have been fully considered but they are not persuasive.

Applicant's principle arguments are

(a) The relief valves in each of Nemser and Goddard are structurally and functionally different since the pressure relief valve of Goddard is a gas pressure relief valve and not a liquid pressure relief valve. The valve of Goddard cannot function as a liquid pressure relief valve.

In response to Applicant's arguments, please consider the following comments.

The 35 U.S.C. 103 rejections as stated above do not suggest that it would have been obvious to substitute the pressure relief valve of Goddard for the pressure relief valve of Nemser. The Goddard reference is merely used as evidence to show that the use of pressure relief valves positioned at an end cap of a filter is known in the art. It would have been apparent to either keep the pressure relief valve of Nemser at the inlet conduit leading to the filter, or, as suggested by Goddard, move Nemser's pressure relief valve so that it is directly connected to the filter endcap. This change in the position of the pressure relief valve is simply a rearrangement of parts that does not result in a configuration that represents a patentable difference over the prior art represented by Nemser. See MPEP 2144.04. Upon review of Goddard, one of ordinary skill would not be motivated to change the pressure relief valve of Nemser so that it is a gas pressure relief valve. One of ordinary skill in the art would be motivated to change the location of Nemser's liquid pressure relief valve in order to position it directly at the filter endcap.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

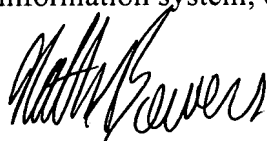
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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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